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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/575,324   | 04/04/2007  | Lewis George Gradon  | 1171/44893/168-PCT-US       | 3633                   |
| 279 7590 08/28/2009<br>Trexler, Bushnell, Giangiorgi,<br>Blackstone & Marr, Ltd.<br>105 West Adams Street<br>Suite 3600<br>Chicago, IL 60603 |             |                      | EXAMINER<br>YOUNG, RACHEL T |                        |
|  |             |                      | ART UNIT<br>3771            | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/575,324 | <b>Applicant(s)</b><br>GRADON ET AL. |  |
|                              | <b>Examiner</b><br>RACHEL YOUNG      | <b>Art Unit</b><br>3771              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/14/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Preliminary Amendment***

1. This office action is responsive to the preliminary amendment filed on 4/10/2006. As directed by the amendment: claims 1-35 have been canceled, and new claims 36-69 have been added. Thus, claims 36-69 are presently pending in the application.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Page 6, line 5 Reference Number 33. Page 8, lines 9 and 10 Reference Number 52. Page 8, line 11 Reference Number 55. Page 8, line 25 Reference Number 59. Page 10, line 21 Reference Number 101. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “103” has been used to designate both “headgear strap” and “first sliding strap”. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The disclosure is objected to because of the following informalities: Page 1, line 9 recites “there are well known variety”, which should be –there are a well known variety-. Page 10, line 9 recites “to that of Figure 11”, which should be –to that of Figure 10-. Page 12, line 28 recites “housing 112”, which should be -housing 122-. Page 13, line 29 recites “Figure 17 an axis”, which should be –Figure 17 shows an axis-. Appropriate correction is required.

### ***Claim Objections***

6. Claims 45, 49, 51-52, 56, 59-60, 62, 65 and 68-69 are objected to because of the following informalities: The above claims are improper due to spelling or grammar or lack of antecedent basis problems. Claim 45 recites in lines 1 and 2 “said second conduit”, which should be –a second conduit-. Claim 49 recites “said fastening means”, which should be –fastening means-. Claim 51 recites “said forehead rest”, which should be –a forehead rest-. Claim 52 recites “connected said forehead rest”, which should be -connected to a forehead rest-. Claim 56 recites “said sliding strap”, which should be –a sliding strap-. Claim 59 recites “let allows”, which should be –yet allows-. Claim 60 recites “said housing”, which should be –a housing-. Claim 62 recites “aims receive”, which should be –arms receive-. Claim 62 recites “supporting”, which should be –support-. Claim 65 recites “rigid pad”, which should be –rigid part-. Claim 68 recites “said backward soft part”, which should be –a backward soft part-. Claim 69 recites “said forward substantially rigid part”, which should be –a forward substantially rigid part-. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 45 recites "wherein said second conduit is more flexible than said second conduit". As best understood, this claim will be examined as - wherein said second conduit is more flexible than said first conduit-. However, clarification is needed and appropriate correction is required.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 36-37, 39, 41, 43-45, 47-49, 53, 58-61 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Hecker et al. (6595214 B1).

As to claim 36, Hecker teaches a device for delivering a supply of gases (Fig. 2) to a user including an interface including a hollow body (1 and 2) (Fig. 2), a gases inlet

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(23) (Fig. 2) and a sealing member (1) (Fig. 2) configured to in use rest against the face of a user, adapted in use to supply gases to said user (Col. 4, ll. 29-31) (Fig. 2), a conduit (5) (Fig. 2) supplying said gases to said interface, the conduit attached to an inlet to the hollow body (Fig. 2), and headgear adapted to attach to said interface and around the head of said user (Col. 5, ll. 3-5), where said conduit includes at least one angular adjustment mechanism (3) (Fig. 2) to allow for angular adjustment of the interface (Col. 3, ll. 14-27).

As to claim 37, Hecker teaches that the angular adjustment means is at least one joint and said joint is a ball and socket joint (Col. 3, ll. 29-32).

As to claims 39 and 41, Hecker teaches that at least one angular adjustment means is a section of flexible conduit (3) (Fig. 2) (Col. 3, ll. 15-27), and that the conduit is supported in relation to said headgear such that any load on said conduit is taken by said headgear and not said interface (Fig. 2).

As to claims 43-45, Hecker teaches that the hollow body has a forehead rest ("forehead plate" 10) (Fig. 2, 3) with harnessing slots (10, 11) (Fig. 3) to secure said hollow body to said headgear, that the conduit includes a first conduit (5) (Fig. 2) connected to a second conduit (3) (Fig. 2) that attaches to the inlet of said interface (Fig. 2), and that the second conduit is more flexible than said first conduit (Col. 3, ll. 14-27).

As to claims 47-49, Hecker teaches that the conduit is attached to the headgear by fastening means ("latching clip" 15) (Fig. 2), that the headgear includes a transverse

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strap (Fig. 3) (Col. 5, ll. 3-5) which in use lies on top of said user's head, and that the transverse strap includes a fastening means (12) (Fig. 3) (Col. 5, ll. 3-5).

As to claim 53, Hecker teaches that the headgear includes a plurality of straps (Col. 5, ll. 3-5) including at least one side strap (Col. 5, ll. 3-5) that the conduit is attached to by the fastening means (12) (Fig. 3) (Col. 5, ll. 3-5).

As to claims 58-59, Hecker teaches that the headgear includes adjustment means ("forehead-plate mount" 9) (Fig. 2, 3) to adjust the vertical distance between the headgear and the interface (Col. 2, ll. 12-17), and that the adjustment means is substantially tubular housing that restrains said conduit yet allows said conduit to move through it (Fig. 2-3) (Col. 2, ll. 12-17).

As to claims 60-61, Hecker teaches that the conduit includes a plurality of detents (Fig. 2) and a housing (9) (Fig. 3) includes a protrusion (Fig. 3) that interacts with said detents when said conduit is moved to adjust the vertical distance between said headgear and said interface (Col. 2, ll. 12-17) (Col. 5, ll. 6-45), and that the headgear includes a transverse strap (Col. 5, ll. 3-5) including a support portion ("collar" 24 and "forehead plate" 10) (Fig. 3) capable of receiving said conduit to support and decouple movement of said conduit from said interface (Fig. 2).

As to claim 63, Hecker teaches that the support portion ("collar" 24 and "forehead plate" 10) (Fig. 3) is an elongate member capable of restraining said conduit (Fig. 2, 3).

***Claim Rejections - 35 USC § 103***



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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker in view of Demers et al. (20020056457 A1).

As to claim 38, Hecker teaches that the at least one joint is two ball and socket joints (Col. 3, ll. 29-32), however is silent regarding them having rectangular profiles to limit pivoting of each of the joints through one axis. However, Demers teaches them having rectangular profiles to limit pivoting of each of the joints through one axis (Fig. 7a). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's ball and socket joints such they have rectangular profiles to limit pivoting of each of the joints through one axis, as taught by Demers, for the purpose of providing a more controlled angular adjustment needed for better comfort for a user.

13. Claims 40, 55 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker in view of Jestrabeck-Hart (6470886 B1)

As to claims 40 and 55, Hecker is silent regarding that the flexible conduit includes a malleable band, and that headgear includes a sling to support said conduit and in use is adapted to connect around said conduit. However, Jestrabeck-Hart teaches that the flexible conduit includes a malleable band (13) (Fig. 6C and 7D), and that headgear includes a sling (13) (Fig. 6C) to support said conduit and in use is

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adapted to connect around said conduit (Fig. 6C). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include a flexible conduit that includes a malleable band, and that the headgear includes a sling to support said conduit and in use is adapted to connect around said conduit, as taught by Jestrabeck-Hart, for the purpose of comfortable retaining the conduit for the user.

As to claim 62, Hecker teaches that the support portion is curved in shape (Fig. 3), however is silent regarding that it has an upper arm and lower arm, the upper arm being more flexible than the lower arm, each of the arms receive the conduit and support the conduit above the headgear. However, Jestrabeck-Hart teaches that it has an upper arm (Fig. 6C) and lower arm (Fig. 6C), and that each of the arms receive the conduit (Fig. 6C) and support the conduit above the headgear (Fig. 6C). Although Jestrabeck-Hart lacks details regarding that the upper arm is more flexible than the lower arm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's headgear such that the upper arm is more flexible than the lower arm since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It also would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include an upper arm and lower arm, and each of the arms receive the conduit and support the conduit above the headgear, as taught by Jestrabeck-Hart, for the purpose of providing more structural support to the respiratory conduit.

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14. Claims 42, 46, 50, 54, 56-57, 64 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker in view of Ging et al. (20030196662 A1)

As to claims 42 and 46, Hecker is silent regarding that there is a sliding connection between said headgear and said interface when said interface is engaged with said user, and that the headgear has a plurality of hook and loop attachments that enable connection of said headgear to said interface. However, Ging teaches that there is a sliding connection ("connector element" 128) (Fig. 1) between said headgear and said interface when said interface is engaged with said user, and that the headgear has a plurality of hook and loop attachments (Page 6, ¶ 120, ll. 10-11) that enable connection of said headgear to said interface. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include that there is a sliding connection between said headgear and said interface when said interface is engaged with said user, and that the headgear has a plurality of hook and loop attachments that enable connection of said headgear to said interface, as taught by Ging, for the purpose of providing structural support tightening or loosening means for the comfort of the user.

As to claims 50 and 54, Hecker's device teaches that the fastening means is a hook and loop attachment (Ging Page 6, ¶ 120, ll. 10-11) and that the headgear attaches to said interface by a sliding strap (Ging "connector element" 128) (Fig. 1).

As to claims 56-57, Hecker's mask is silent regarding that a sliding strap attaches to said conduit to provide support to said conduit, and that the device includes an additional strap attachment between said headgear and said conduit to restrain said

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conduit from moving. However, Ging teaches that a sliding strap attaches to a conduit to provide support to a conduit (Fig. 1), and that the device includes an additional strap attachment between said headgear and said conduit to restrain said conduit from moving (96) (Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include that the sliding strap attaches to a conduit to provide support to a conduit, and that the device includes an additional strap attachment between the headgear and the conduit to restrain the conduit from moving, as taught by Ging, for the purpose of providing structural support tightening or loosening means for the comfort of the user.

As to claim 64, Hecker teaches that the headgear is comprised of a forward substantially rigid part (9) (Fig. 3) (Col. 5, ll. 64-65), however is silent regarding a backward soft part. Ging teaches a backward soft part (84) (Fig. 1) (Page 6, ¶ 120, ll. 39-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include a backward soft part, as taught by Ging, for the purpose of providing comfort to the user.

As to claim 67, the modified Hecker is silent regarding that the backward soft part is formed of a stretchable, breathable material. However, Ging teaches that the backward soft part is formed of a stretchable, breathable material (Page 6, ¶ 120, ll. 7-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's headgear to include that the backward soft part is formed of a stretchable, breathable material, as taught by Ging, for

the purpose of providing structural support tightening or loosening means for the comfort of the user.

As to claim 68, Hecker is silent regarding that headgear includes tightening means that allows the adjustment of a backward soft part. However, Ging teaches that headgear includes tightening means (150) (Fig. 1) that allows the adjustment of a backward soft part (84) (Fig. 1) (Page 6, ¶ 120, ll. 39-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear such that the headgear includes tightening means that allows the adjustment of a backward soft part, as taught by Ging, for the purpose of providing structural support tightening or loosening means for the comfort of the user.

15. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker in view of Sprinkle et al. (7290546 B2).

As to claim 52, Hecker is silent regarding that the transverse strap is connected to a forehead rest by an adjustable glider mechanism, however Sprinkle teaches that the transverse strap (coming out of 92) (Fig. 1) is connected to a forehead rest (54) (Fig. 1) by an adjustable glider mechanism ("vertical member" 56) (Fig. 1, 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include that the transverse strap is connected to the forehead rest by an adjustable glider mechanism, as taught by Sprinkle, for the purpose of providing adjustment for the user to enhance the comfort.

16. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker in view of McDonald et al. (2001/0042547 A1).

As to claim 51, Hecker teaches that a transverse strap is connected to a forehead rest (Fig. 3), however is silent regarding by a telescopic extension mechanism. However, McDonald teaches a telescopic extension mechanism (Page 2, ¶ 27) (Fig. 5). Although the telescopic mechanism is not used in conjunction with a forehead rest, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear such that a transverse strap is connected to a forehead rest by a telescopic extension mechanism, as taught by McDonald, for the purpose of providing a proper location for the forehead rest.

17. Claims 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Ging in view of Sprinkle.

As to claims 65-66, Hecker's modified device teaches that the forward substantially rigid part includes a substantially rigid layer (9) (Fig. 3) (Hecker Col. 5, ll. 64-65). Hecker is silent regarding, and a padding layer that is removable from the rigid layer. However, Sprinkle teaches a padding layer (52) (Fig. 1) that is removable (Col. 4, ll. 16-26) from the rigid layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's mask to include a padding layer that is removable from a rigid layer, as taught by Sprinkle, for the purpose of providing comfort to the user and ease of manufacturing.

18. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Ging in view of Bordewick et al. (2004/0035427 A1).

As to claim 69, Hecker's modified device teaches the tightening means (Ging 150) (Fig. 1) where a length of elastic (Ging 96) (Fig. 1) (Page 2, ¶ 23, ll. 12) is attached

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to a forward substantially rigid part (9) (Fig. 3) (Hecker Col. 5, ll. 64-65) but extends over a backward soft part (Ging 84) (Fig. 1) (Page 6, ¶ 120, ll. 39-41). The modified Hecker's mask is silent regarding a toggle which said length of elastic is capable in use of being pulled through to tighten said backward soft part in relation to a forward substantially rigid part. However, Bordewick teaches a toggle ("quick-sizing cord" 7) (Fig. 1) which said length of elastic is capable in use of being pulled through to tighten said backward soft part in relation to said forward substantially rigid part (Page 2, ¶ 23, ll. 27-29) (Page 2, ¶ 17, ll. 1-4).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lithgow et al. (2002/0026934 A1) too a facemask with a plurality of straps and patient interface and Bauer (WO 90/48878) to a respiratory interface with a conduit, straps and an adjustment mechanism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/R. Y./  
Examiner, Art Unit

/Danton DeMille/  
Primary Examiner, Art Unit 3771